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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,385	08/24/2001	Scott Levine		3458

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/17/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/939,385	Applicant(s) LEVINE, SCOTT	
	Examiner Traviss C McIntosh	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other: _____

Detailed Action

Information Disclosure Statement

Acknowledgement is made of the receipt of the information disclosure statement filed and the references have been taken into consideration.

Specification

The use of the trademarks Xenical™, Ultra Slim Fast™, Herbalife Thermojetics™, and others have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on the bottom line of page 11. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 14 and 15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant, claims 14 and 15 depend from claim 13

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wherein claim 13 is drawn to a method of administering a nutritional supplement. Claims 14 and 15 do not provide any limitations to a method of administering a composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 18-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "ultra-high" in claims 1 and 18 is a relative term which renders the claim indefinite. The term "ultra-high" is not defined by the claim, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Incorporation of the numerical value meant to be encompassed by the phrase "ultra-high" into the claim would be seen to obviate the rejection instantly at hand.

The term "ultra-fiber" in claims 13 and 21 is a relative term which renders the claims indefinite. The term "ultra-fiber" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Deletion of the word "ultra" would be seen to obviate the rejection instantly at hand.

Regarding claim 1, the phrase "namely" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP

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§ 2173.05(d). Deleting “namely” and replacing with “which are” would be a more favorably considered way to describe the three members of the group specifically.

Claim 13 recites the limitation "said nutritional supplement" in line one. There is insufficient antecedent basis for this limitation in the independent claim. Deletion of “said” would be seen to obviate the rejection instantly at hand.

Claims 3, 12, 19, and 22 are indefinite where they recite a group within a group or overlapping groups. It is unclear what is meant to be encompassed by the claims wherein they recite groups which substantially overlap as it is unclear as what is meant to be encompassed by the broader group. Claim 3 recites, “further including one or more fibers from the group consisting of gums, grains, celluloses, hemicelluloses, lignins, mucilages, and fibers derived from plant, fungi, and yeast.” Reciting fibers derived from a plant in one group and gums, grains, and cellulose in another leaves uncertainty as to what is meant to be excluded or included in the group drawn to fibers derived from plants, as gums, grains, and celluloses are derived from plants. Likewise, claims 12, 19, and 22 recite herbs, botanicals and teas. Is there a limitation in one group which includes different ingredients which may be encompassed by the other groups? Clarity is respectfully requested.

Claims 19, 20, 22, and 23 all recite the limitation "the composition according to claim X..." in first line. There is insufficient antecedent basis for this limitation in these claims as the claims from which these depend are method claims which do not recite a composition. The rejection would be obviated by deleting “the composition according to claim X...” and replacing with “the method according to claim X wherein the supplement...”.

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Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Independent claim 13 is drawn to a method of administering a nutritional supplement, but does not provide any steps for administering a nutritional supplement, nor does the claim provide a host which is to be administered the supplement.

All claims which depend from an indefinite claim are also indefinite. *Ex Parte Cordova*, 10 U.S.P.Q.2d 1949, 1952 (P.T.O. Bd. App. 1989).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 10 – 12, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Leitz et al. (US Patent 4,877,627).

The claims of the instant invention are drawn to a nutritional supplement comprising a mixture of three types of fiber, guar, oat, and psyllium, and a flavoring agent. The supplement further includes one or more fibers (gums, grains, celluloses, hemicelluloses, lignins, mucilages), visual and organoleptic agents (coloring agent, preservative, thickening agent, thinning agent, emulsifier), the flavoring agent is a flavorant or sweetener, and the supplement is provided in the

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form of solids, liquids, powders, puddings, or snack bars. Additionally, the instant application is drawn to a method of treating cardiovascular disease by administering the supplement supra.

Leitz et al. disclose a composition which comprises oat, psyllium, guar, and additional fibers (table 1, column 3) to provide a composition which can be administered to mammals to provide a balanced intake of dietary fiber (column 2, lines 57-62). A pharmaceutically acceptable dye, sweetening agent, and flavoring agent may be included into the composition wherein the composition is in the form of a liquid dosage (column 5, lines 6-12). Starch may additionally be added (column 4, line 55). Leitz et al. additionally disclose that the soluble dietary fiber in their composition is associated with a reduction of low-density lipoproteins and serum cholesterol (column 1, lines 45-55).

The composition and methods of use as disclosed in Leitz et al. is seen to anticipate the composition and methods of use as set forth in claims 1, 3, 5, 6, 10 – 12, 18, and 20 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Leitz et al. (US Patent 4,877,627) and Gori et al. (US Patent 4,784,861).

The claims of the instant invention are drawn to the supplement as noted supra, additionally wherein the composition contains 1-15g guar, 1-15g oat, and 0.5-10g psyllium. The supplement can further include a liquid admixed with the fibers wherein the total fiber is at least 7 grams of fiber per 8-20oz serving (beverage). Additionally, antioxidants, tea, vitamins, herbs, botanicals, minerals, electrolytes and coenzymes may further be added to the composition. Moreover, the claims of the instant application are drawn to a method of serving at least seven grams of fiber to an individual comprising administering supplement to individual in need thereof in two doses, each containing at least seven grams of fiber per dose and a method of limiting ingested toxins, carcinogens, and heavy metals through reducing absorption and speeding transit out of the body by administering the supplement.

Leitz et al. teach the composition as noted above and which is incorporated herein as reference. Additionally, Leitz et al. teach that national experts have suggested that as much as 25-40g/day of fiber could be beneficial in the human diet. What is not taught by Leitz et al. is the limitations of 1-15g guar, 1-15g oat, and 0.5-10g psyllium incorporated in the composition nor for the use in serving at least seven grams of fiber to an individual or limiting ingested toxins, carcinogens, and heavy metals through reducing absorption and speeding transit out of the body.

Gori et al. teach of formulations used as natural weight control substances (column 1, line 67 – column 2, line 2). The formulations of the Gori et al. may be provided in powdered forms of about 0.5 – 5g each and an average person may take up to ten doses a day (column 3, lines 10-13 and 50-57). A ten gram fiber formulation of Gori et al. comprises 3g +/-15% oat, 2g +/-15% guar, and 1g +/-15% psyllium (table in column 4). Additionally, Gori et al. teach that intestinal absorption of nutrients can be influenced by modifying the rates at which food enters and leaves the stomach, and high fiber foods may require longer periods for ingestion, thereby modifying the rates of gastric filling, and therefore emptying (column 1, lines 42-59).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Gori et al. and Leitz et al. to provide a fibrous composition which would be capable of providing the recommended dosage of 25-40g of fiber a day (Leitz et al., column 2, lines 5-9) in which a 35g composition as prepared by Gori et al. according to the table in column 4 would comprise 10.5g oat, 7g guar, and 3.5g psyllium (all +/- 15%). It would be obvious to add flavorants as taught by Leitz et al. into the composition of Gori et al. as it is known in the art to add flavorings and sweeteners to make substances which are to be taken orally to make them more palatable. Further, it is known by one of ordinary skill in the art that fiber detoxifies toxic substances and frequently bind to heavy metals and toxins in the stomach. One would be motivated to combine these teachings to provide a method and formulation which would allow an individual in need of treatment or nourishment the proper dosage of fiber in an easy to eat or drink form. One would be motivated to include vitamins and minerals in foodstuffs as consumers frequently look for products which provide health benefits, especially in diet foods, as there is additionally normally a limited amount of food which the

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individual is taking in during their diet, therefore, the more vitamins and minerals incorporated in the diet food supplement, the more pleasing it is to the consumer.

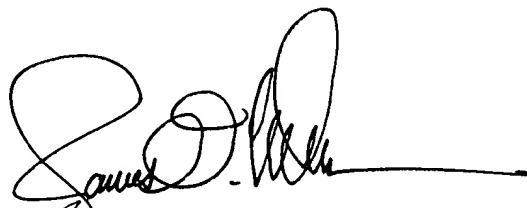
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh
December 12, 2002



James O. Wilson
Supervisory Patent Examiner
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